UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,036	03/16/2004	Stephen D. Pacetti	50623.311	7967

7590 03/30/2009

Victor Repkin
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,036	PACETTI, STEPHEN D.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *7-12,16-18,28-33 and 37-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,13-15,19-27,34-36,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

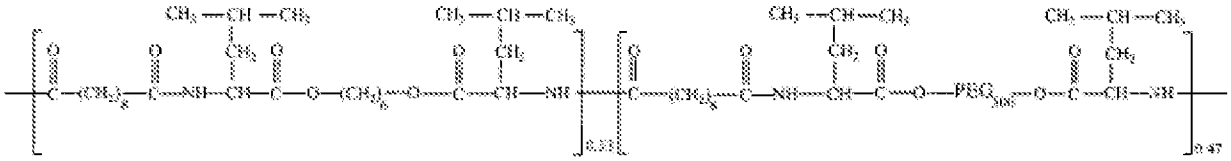
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

To summarize the current election, applicant elected the species where the polymer is polymer 23 (depicted below) and the reagents used to product it are compounds 1, 5, and 9.



Claims 25 and 35-36 were previously withdrawn from consideration but based upon applicant's election are examined in this Office action. Thus the claims withdrawn from consideration are 7-12, 16-18, 28-33, and 37-39.

Claim Objections

Claims 20 and 41 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 19 and 40 recite a polymer of the form

$$-[M\text{-}P]_m\text{-}[M\text{-}Q]_n- \quad \text{or} \quad -[M_1\text{-}P]_p-$$

where M, M_1, P, and Q are chemical moieties, m is between 5 and 1800, n is between 1 and 800 and p is between 4 and 1500. Based upon the definitions provided by these claims, ED_{600} is not an option for any portion of M, M_1, P, or Q. Thus the recitation of

polymers by claims 20 and 41 where ED_{600} is a present (e.g. compounds 19 and 41) do not further limit claim 19 and 40.

Claims 20 and 41 are also objected to because of a stray parenthesis present beside the "n" subscript in compound 28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

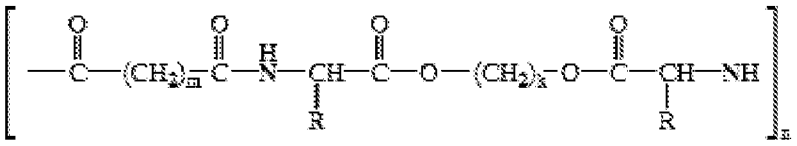
Claims 1, 3-6, 13-15, 19-21, 23-27, 34-36, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsarava et al. (US PGPub No.

2002/0015720) in view of Katsarava et al. (Journal of Polymer Science: Part A 1999 37:391-407 – henceforth Katsarava et al. reference B – see IDS), and Nagata (Polymer International 1997 42:33-38).

Claims 1, 3-6, and 13-15 recite a product-by-process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Here the only structure conferred by the process steps of the claims is the chemical structure of the polymer in the coating. Thus the prior art need only teach or make obvious the polymer structure in the coating, regardless of the process used to produce, it in order to meet the limitations drawn to the polymeric material.

Katsarava et al. teach biodegradable poly(ester amide) polymers made from amino acids that are used to coat implantable medical devices (see paragraphs 16, 45, and 47). In particular, the compounds are made from the polymerization of a diol (D) with a dicarboxylic acid (C) and an alpha-amino acid (A) (see paragraph 16). The resulting polymers have monomers of the form DACA (formula II) or CADA (formula I). In particular, poly(ethylene glycol) as well as a C_6 alkylene diol is envisioned as diols (D) (see paragraphs 10-14, 17, and 19-21; instant claims 1, 3, 13, 19-21, 24, 34, and 40-41). Leucine is envisioned as a particularly preferred amino acid (A) (see paragraphs

10-14 and 25; instant claims 1, 3-6, 13-15, 19-21, 24-27, 34-36, and 40-41). A linear C_8 α, ω dicarboxylic acid is taught as a preferred dicarboxylic acid (C) (see paragraphs 10-14, 18-19, and 22; instant claims 1, 19-21, and 40-41). A particular set of polymers with CADA configured monomers that were known are depicted in formula I (see below)



[0011] where

[0012] k=2, 3, 4, or 6

[0013] m=4 or 8, and

[0014] R=$CH(CH_3)_2$, $CH_2CH(CH_3)_2$, $CH(CH_3)CH_2CH_3$, $(CH_2)_3CH3$, $CH_2C_6H_5$, or $(CH_2)_2SCH_3$.

Katsarava et al. do not explicitly teach the elected polymer with two different CADA monomers such that one has poly(ethylene glycol) as the diol unit while the other has a hexyl moiety as the diol unit .

Katsarava et al. reference B teaches poly(ester amide) polymers that are composed of CADA monomers and are the form of formula I (see Schemes 1-3). One particular polymer (termed 8-L-Leu-6) taught has m = 8, k=6 and R = iso-butyl thereby teaching a monomer where C is a linear C_8 α, ω dicarboxylic acid, A is leucine, and D is a C_6 alkylene (hexyl) diol (see Table II compound 10). This is one of the CADA monomers in the elected polymer. This polymer is produced by the polymerization of a monomer constructed by the condensation of an amino acid with a diol whose product is then reacted with a dicarboxylic acid (see Schemes 1 and 2; instant claims 21 and

24-27) Katsarava et al. reference B also teaches that degradation of their polymers is enzymatically catalyzed (see table VIII).

Nagata teaches that aliphatic polyesters were known degradable synthetic polymers whose degradation could be uneven due to their hydrophobicity and high melting point (see page 33 column 1 paragraph 1). Nagata also teach that the introduction of poly(ethylene glycol) (PEG) segments into the polymer backbone would solve this issue (see page 33 column 1 paragraph 1). Nagata demonstrates that the presence of a low molecular weight PEG (PEG 200) allows for degradation to occur via both a standard hydrolytic route and an enzymatically catalyzed route (see figure 4). In addition, the length of the PEG chain and the proportion of PEG in the polymer determine the polymers susceptibility to enzyme catalyzed degradation (see figure 4).

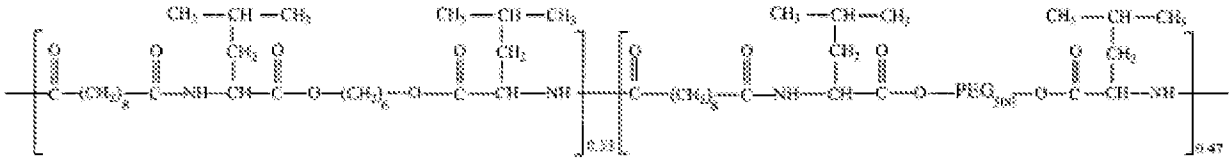
Polymers composed of CADA monomers were known at the time of the invention. In addition, the selection of a linear C_8 α, ω dicarboxylic acid for C, leucine for A, and a hexyl diol or PEG for D were specifically taught. The 8-L-Leu-6 polymer taught by Katsarava et al. reference B could be classified as an aliphatic polyester as it has two aliphatic chains within its backbone. Based on the teachings of Nagata, the inclusion of PEG into the back bone of aliphatic polyesters allows for its degradation to be smoother and controlled by two mechanisms. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a medical article with a poly(ester amide) coating as taught by Katsarava et al. where the coating polymer was the block copolymer of two CADA monomers resulting from the coupling of a 8-L-Leu-6 block to a similar block where PEG is exchanged for the hexyl diol. Further,

such an incorporation would allow for more flexibility in controlling the rate of degradation (e.g. via modification of the monomer mole ratio) in the resulting polymeric coating material. Since condensation of a diol with an amino acid was a known synthetic route for producing the diol-diamines in the CADA monomer units and PEG was a known diol, it would have been obvious to one of ordinary skill in the art at the time of the invention to use this same route to produce the PEG-diester-diamine (a PEG version of a diol-diamine where a PEG-diester is the "diol") for the PEG containing CADA monomer (see instant claim 34). To produce the elected polymer made by obvious by the combination of both Katsarava et al. references and Nagata there would need to be a molar amount of the dicarboxylic acid equal to the total molar amount of the diol-diamine and the PEG-diester-diamine such that each would have one dicarboxylic acid moiety. So if X is the molar amount of diol-diamine and Y is the molar amount of PEG-diester-diamine, there would need to be A + B moles of dicarboxylic acid (see instant claim 23). Although Katsarava et al. in view of Katsarava et al. reference B and Nagata do not explicitly teach the proportion of monomers to use or a PEG 300 chain, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters (monomer/reactant proportions and PEG chain length) as a matter of routine experimentation. Thus it would have been obvious to one of ordinary skill in the art to employ the elected polymer as a coating on an implantable substrate of a medical article as well as fabricate the article via the claimed method. Therefore claims 1, 3-6,

13-15, 19-21, 23-27, 34-36, and 40-41 are obvious over Katsarava et al. in view of Katsarava et al. reference B and Nagata.

Claims 1-2 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsarava et al. in view of Katsarava et al. reference B and Nagata. as applied to claims 1, 3-6, 13-15, 19-21, 23-27, 34-36, and 40-41 above, and further in view of Michal (US PGPub No. 2002/0120326).

Katsarava et al. in view of Katsarava et al. reference B and Nagata make obvious a coated medical article and its claimed method of production where the polymer coating includes the poly(ester amide)



Although this modified reference does teach the medical article to be one that contacts blood, it does not explicitly teach the article is a stent. Michal teaches stents with a series of polymeric coatings (see Katsarava et al. paragraph 47). In particular, Michal teaches biodegradable polymers being used as an overcoat on stents and specifically name poly(ester amide)s as envisioned polymers for such a purpose (see paragraphs 15 and 26; instant claims 2 and 22). In view of the teachings of Katsarava et al. in view of Katsarava et al. reference B and Nagata that the poly(ester amide)s can be used in implanted devices that contact blood, it would have been obvious to one of ordinary skill in the art at the time of the invention to select a stent as one such device. Therefore

claims 1-2 and 21-22 are obvious over Katsarava et al. in view of Katsarava et al. reference B, Nagata and Michal.

Response to Arguments

Applicant's arguments, filed April 9, 2008, with respect to the rejection of claims 1-6, 13-15, 19-24, 26-27, 24, 40, and 41 under 35 USC 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made in view of Katsarava et al. in view of Katsarava et al. reference B, and Nagata as well as Katsarava et al. in view of Katsarava et al. reference B, Nagata and Michal.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615